

CENTER FOR VETERINARY MEDICINE

OFFICE OF SURVEILLANCE AND COMPLIANCE

DIVISION OF COMPLIANCE

1. Division of Compliance
2. Authority and Effective Date

1. DIVISION OF COMPLIANCE (HFV-230).

- a. Coordinates the preparation of evidence concerning withdrawal/refusal to approve animal drugs and the documentation for a formal evidentiary hearing; coordinates the preparation of administrative and evidentiary records for a hearing.
- b. Develops, monitors, and evaluates the Center's Bioresearch Monitoring Programs and their investigative and regulatory follow-up. Manages the application integrity policy.
- c. Develops, monitors, and evaluates the Center's compliance and surveillance programs pertaining to tissue residues and National Drug Residue Milk Monitoring.
- d. Evaluates regulatory approaches to human food safety concerns including monitoring the prevalence of violative levels of harmful drugs and chemicals in meat and poultry based on findings reported to FDA/CVM by USDA/FSIS and developing strategies designed to prevent food safety problems associated with pathogens and residues.
- e. Coordinates and prepares compliance and enforcement oriented replies to inquiries from consumers, State and Federal governments, Congress, industry, etc.
- f. Advises on regulatory and administrative policy issues and develops enforcement strategies involving animal drugs, feeds, feed additives, veterinary medical devices, and other veterinary medical products; prepares and issues guidance to the Field Offices.
- g. Preliminarily reviews Establishment Inspection Reports, investigations, complaints and other information on regulated products. Coordinates investigative and regulatory follow-up through consultation with management, legal and scientific advisors. Reviews proposed regulatory actions submitted by the Field Offices and recommends whether such actions should be pursued further by the Agency.

2. AUTHORITY AND EFFECTIVE DATE. The functional statements for this Division were approved by the Deputy Commissioner for Operations on January 23, 1997.